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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534;038	05/06/2005	Michel Serpelloni	0600-1040	9708

466 7590 12/07/2007
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EXAMINER

SASAN, ARADHANA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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12/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,038

Applicant(s)

SERPELLONI, MICHEL

Examiner

Aradhana Sasan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-23 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/6/05 and 8/1/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Application

1. Claims 1-9 were canceled.
2. Claims 10-23 are included in the prosecution.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 5/6/05 and 8/1/05 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

Claim Objections

5. Claim 10 is objected to because of the following informalities: line 7 of claim 10 recites the phrase "said branched maltodextrins content is of between". It should recite: "said branched maltodextrins content is between". Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukuda et al. (US 2002/0146487) in view of Fouache et al. (US 6,630,586).

The claimed invention is a method for preparing granules of active substances containing dietary fiber. The method consists of granulating a mixture of the active substances and branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass M_n at most 4500g/mol. The branched maltodextrins content is between 3 and 13% by weight of the mixture to be granulated.

Tsukuda teaches "a method for preparing an easily dispersible granule of soybean protein, which comprises the step of granulating powdery soybean protein while the powder is sprayed with an aqueous solution containing a carbohydrate which is not readily digestible, characterized by using at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein ... the granulation is fluidized bed-granulation" (Page 2, [0020]). A "dry blend comprising soybean protein and a not readily digestible carbohydrate is prepared, and is then sprayed with lecithin in water to produce a lecithin-coated soybean protein carbohydrate blend. The water is then removed ... by drying. Other components, including nutraceutical components ... can be combined with the protein/carbohydrate/lecithin blend to further supplement the nutritive value of the product" (Pages 2-3, [0021]). The method steps are: "stirring and fluidizing powdery soybean protein according to an appropriate method, spraying the stirred and fluidized powdery soybean protein with the carbohydrate in the form of an aqueous solution, followed by appropriately drying the spray-coated soybean protein

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powder after the spraying step or simultaneous with the spraying operation to thus coat the surface of the soybean protein powder with the carbohydrate and to simultaneously granulate the soybean protein" (Page 3, [0030]). "After completion of the drying, the resulting granules are passed through a sieve, for instance, to make the particle size uniform and then packaged" (Page 3, [0036]). "Examples of the not readily digestible carbohydrates commercially available are ...Fibersol 2 (trade name of hardly digestible dextrin available from Matsutani Industry Co., Ltd., ..." (Pages 5-6, [0055]).

Tsukuda does not expressly teach branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass M_n at most 4500g/mol.

Fouache teaches branched maltodextrins with "22 and 35% ... glucosidic linkages 1→6, a content of reducing sugars lower than 20%, a polymolecularity index lower than 5 and a number molecular weight M_n at most equal to 4500g/mole" (Col. 2, lines 37-42). An acariogenic composition comprising branched maltodextrins and at least one polyol (chosen from sorbitol, mannitol, xylitol and maltitol) is disclosed (Col. 4, lines 15-19). "The content of glucosidic linkages 1→6, of between 22 and 35%, gives the branched maltodextrins ... a character of indigestibility, the consequence of which is to reduce their calorific value by preventing their assimilation at the level of the small intestine" (Col. 2, lines 45-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of granulating a powder (soybean protein) while

the powder is sprayed with an aqueous solution containing a carbohydrate which is not readily digestible, as taught by Tsukuda, combine it with the branched maltodextrins as the carbohydrate which is not readily digestible, as taught by Fouache, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Fouache teaches that the branched maltodextrins are indigestible and a further motivation is that by using the branched maltodextrins, a low calorie composition can be prepared.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 10, the method for preparing granules would have been obvious to one skilled in the art over the method for preparing granules taught by Tsukuda (Page 2, [0020]). The step of granulating active substances would have been obvious over granulating the powdery active substance (powdered soybean protein) as taught by Tsukuda (Page 2, [0020]). The step of mixing the active substance with branched maltodextrins would have been obvious over mixing or dry blending soybean protein and a not readily digestible carbohydrate as taught by Tsukuda (Pages 2-3, [0021]), in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The content of the branched maltodextrins (between 3 and 13% by weight of the

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mixture to be granulated) would have been obvious over the “at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein” taught by Tsukuda (Page 2, [0020]).

Regarding instant claims 11-16, the limitation of the active substances selected from starches and starch derivatives (claim 11), dextrins (claim 12), hydrogenated starch hydrolysates (claim 13), polyols (claims 14-15) and sugars, strong sweeteners and pharmaceutical active principles (claim 16) would have been obvious to one skilled in the art as active substances for granulation over the granulation method taught by Tsukuda (Page 2, [0020]), in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). One skilled in the art would know that granulation is used as a method to improve the flow characteristics, and reduce dustiness of a powder. One skilled in the art would know that granulation is a step carried out prior to tableting and therefore, would use substances such as starch and starch derivatives, dextrins, hydrogenated starch hydrolysates, polyols, sugars and strong (or intense) sweeteners as active substances for granulation.

Regarding instant claim 17, the method steps would have been obvious over the method of mixing the dry blend of the powdery active substance and the “not readily digestible carbohydrate” with lecithin and water (18.98%), drying and passing the granules through a sieve as taught by Tsukuda (Page 3, [0036] and Page 8, Example 5, [0098]).

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Regarding instant claim 18, the limitation of approximately 5% maltodextrin would have been obvious over the "at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein" as taught by Tsukuda (Page 2, [0020]).

Regarding instant claim 19, the limitation of 10% of water to form the wet powders would have been obvious over the amount of water (18.98%) taught by Tsukuda (Page 2, [0020]). Although Tsukuda does not expressly teach 10% of water, one with ordinary skill in the art would modify the level of water during the process of routine experimentation in order to optimize the wet granulation process. The recited percentage would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 20, the solution of branched maltodextrins would have been obvious over the "aqueous solution containing a carbohydrate which is not readily digestible" as taught by Tsukuda (Page 2, [0020]) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The limitation of the solids content would have been obvious over the 10% of "carbohydrate which is not readily digestible" used by Tsukuda (Page 7, Example 1 and Page 8, Table 1). The limitation of spraying the solution of branched maltodextrins onto the powder of active substances and recovering and drying the granules would have been obvious over the spraying of the carbohydrate solution on the active powder (soybean protein) and drying the granules, as taught by Tsukuda (Page 7, [0071]).

Regarding instant claim 21, the solids content of 25% of the solution of branched maltodextrins would have been an obvious variant over the solids content taught by

Tsukuda (Page 7, Example 1 and Page 8, Table 1) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42), unless there is evidence of criticality or unexpected results.

Regarding instant claim 22, the content of approximately 5% of the solution of branched maltodextrins would have been obvious over the "at least 5 parts by weight of the carbohydrate per 100 parts by weight of the powdery soybean protein" as taught by Tsukuda (Page 2, [0020]).

Regarding instant claim 23, the use of branched maltodextrins as a granulation binder would have been obvious over the "carbohydrate which is not readily digestible" as taught by Tsukuda (Page 2, [0020]).

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


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